(i) Printed Pages: 4 Roll No. .....

(ii) Questions : 9 Sub. Code : 3487

Exam. Code : 0438

M.Sc. Bio-Technology 4th Semester

(2054)

DRUG DESIGNING AND DRUG DELIVERY

Paper : MBIO–402

Time Allowed : Three Hours] [Maximum Marks : 80

Note :—(1) Attempt **FIVE** questions in all.

(2) Question No. **1** is compulsory.

(3) Attempt **ONE** question from each Section.

1. (1) Differentiate "absorption" and "distribution" processes in drug pharmacokinetics.

(2) Define "partition coefficient" and its significance in drug pharmacokinetics.

(3) What is "volume of distribution" and how can it be inferred from C vs. T data ?

(4) What is a prodrug and how does it aid in targeted drug delivery ?

(5) Describe two types of trial designs commonly used in clinical research.

(6) What is a control group and why is it important in clinical trial design ?

(7) Define "modified release therapy" and mention one of its potential advantages.

(8) Describe a controlled release system that utilizes external or internal stimulation. 8×2=16

SECTION—A

2. (a) Explain the role of efflux transporters in the absorption and distribution of drugs within the human body. Give examples of how they can affect drug efficacy. 8

(b) Outline the differences between single dose and multiple dose pharmacokinetic models. Discuss how steady-state concentration is achieved in multiple dose regimens. 8

3. (a) Describe the methodology and application of Quantitative Structure-Activity Relationships (QSAR) in drug design. How advancements in 3D QSAR have enhanced this process ? 8

(b) Discuss the application of pharmacophore modelling in virtual screening during the drug discovery process. How does it aid in identifying potential leads ? 8

SECTION—B

4. (a) Explain the pharmacokinetic parameters that can be derived from C vs. T plots following intravenous drug administration. How do these parameters influence dosing schedules ? 8

   (b) Explain the role of molecular complexes in drug delivery systems. Include examples of how complexation can improve drug solubility and efficacy. 8

5. (a) Outline the process of evaluating drug toxicity using in vitro assays. How does this process inform on the safety profile of a drug ? 8

   (b) How can the stability of a drug complex be measured ? Provide examples of techniques used in this assessment. 8

SECTION—C

6. (a) Explain the objectives of Phase II clinical trials and how they differ from Phase I trials in terms of design and outcomes. 8

   (b) Discuss the differences between New Drug Applications (NDA) and Abbreviated New Drug Applications (ANDA) in the context of the FDA approval process. 8

7. (a) Discuss the techniques used for the blinding of drug products in clinical trials. How do these techniques impact the validity of the trial results ? 8

(b) Explain the strategies used to control bias in clinical trials. Why is the control of bias important for trial outcomes ? 8

SECTION—D

8. (a) Explain the mechanism behind dissolution-controlled release systems and how they differ from diffusion-controlled systems ? 8

(b) Explain the use of bioadhesives in drug delivery systems and their advantages for site-specific drug administration. 8

9. (a) Compare and contrast colloidal drug carriers, nanoparticles and liposomes in terms of their characteristics and applications in targeted drug delivery. 8

(b) Explain the problems associated with conventional multi-dose therapy and how modified release therapy can address these issues ? 8